

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



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Applicant's or agent's file reference PCA50104-HMY	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/KR2005/000422</b>	International filing date( <i>day/month/year</i> ) <b>16 FEBRUARY 2005 (16.02.2005)</b>	Priority date ( <i>day/month/year</i> ) 17 FEBRUARY 2004 (17.02.2004)	
International Patent Classification (IPC) or national classification and IPC  <b>A61K 47/38(2006.01)i, A61P 13/08(2006.01)i</b>			
Applicant  <b>HANMI PHARM. CO., LTD. et al</b>			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand  <b>01 NOVEMBER 2005 (01.11.2005)</b>	Date of completion of this report  12 JANUARY 2006 (12.01.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  LEE, Mi Jeong  Telephone No. 82-42-481-5601 

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2005/000422

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
  
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
  - ☒ the international application as originally filed/furnished
  
  - ☐ the description:
    - pages \_\_\_\_\_ as originally filed/furnished
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  
  - ☐ the claims:
    - pages \_\_\_\_\_ as originally filed/furnished
    - pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  
  - ☐ the drawings:
    - pages \_\_\_\_\_ as originally filed/furnished
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
    - pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
  
  - ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
  
3. ☐ The amendments have resulted in the cancellation of:
  - ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, Nos. \_\_\_\_\_
  - ☐ the drawings, sheets \_\_\_\_\_
  - ☐ the sequence listing (*specify*): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
  
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - ☐ the description, pages \_\_\_\_\_
  - ☐ the claims, Nos. \_\_\_\_\_
  - ☐ the drawings, sheets \_\_\_\_\_
  - ☐ the sequence listing (*specify*): \_\_\_\_\_
  - ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1 - 11	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 11	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

The following documents are referred to in this report:

D1: US 6569463 B2 (27. 05. 2003)

D2: US 6638535 B2 (28. 10. 2003)

#### 1. Novelty and Inventive Step

Claims 1-5 of the present invention relate to a composition for oral administration comprising tamsulosin, PVA, and HPMC.

Claims 6-11 of the present invention relate to sustained release granules comprising tamsulosin, PVA, HPMC, and a granulating agent such as microcrystalline cellulose.

D1 discloses a solid pharmaceutical composition for improved delivery comprising tamsulosin and encapsulation coat comprising hydrophilic surfactants, lipophilic surfactants, and triglycerides.

D2 discloses spherical pellets comprising microcrystalline cellulose and active constitute such as tamsulosin.

None of D1 and D2 discloses the said compositions comprising tamsulosin, PVA, HPMC, and optionally a granulating agent such as microcrystalline cellulose in the claims 1-11 of the present invention.

There is no implication or suggestion to lead those who skilled in the art to expect that the two or three elements of the present composition can be used together and the resultant composition can show an excellent stability and a sustained-release pattern in D1 and D2.

Therefore, the novelty and inventive step of claims 1-11 in the present invention can be acknowledged over D1 and D2 [Article 33(2) and 33(3) PCT].

#### 2. Industrial Applicability

The subject-matter of claims 1-11 appears to be industrially applicable [Article 33(4) PCT].

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

There is no description on the title of each example, e.g. "Example 1", "Example 2", etc.